

## REMARKS

Claims 5, 43 and 47 remain pending herein.

Attached hereto as page 6, pursuant to Rule 1.121(c)(1)(ii), is a marked-up version of the amended claims.

Claim 5 (from which claims 43 and 47 each depend) has been amended as set forth above to recite a method comprising administering a therapeutic vaccine comprising venom and at least one adjuvant.

The treatment according to the claimed invention is based on the discovery that it is the *anti-serum* to venom, generated upon administration of venom to a patient, which fights cancer cells. That is, the cancer cells “look like” venom, and as a result, the anti-serum to venom attacks cancer cells in a way which is similar to the way it attacks venom when such venom is present in the patient. By including adjuvant, a smaller amount of venom can be administered to the patient, and the adjuvant stimulates the patient’s immune system such that the patient’s immune system can see the venom and react to it, thereby generating the anti-serum for fighting or preventing neoplasm or neoplastic development. Where venom was employed as an active ingredient, higher amounts of venom needed to be used, and as a result patients developed other conditions (e.g., anaphylactic shock) which necessitated discontinuing therapy or reducing the dosage of venom to an amount at which useful results were not obtained.

Claims 5, 43, 44, 46 and 47 were rejected under 35 U.S.C. § 112, first paragraph. The February 26, 2003 Office Action contains allegations that the present specification does not provide an enabling description of a method of preventing neoplastic development comprising administering phospholipase A2 alone.

As set forth above, claim 5 has been amended to delete coverage of preventing neoplastic development by administering phospholipase A2 (or part thereof) alone. Claim 5 (from which claims 43 and 47 each depend) recites a method comprising administering a therapeutic vaccine comprising venom and at least one adjuvant.

Accordingly, the alleged basis for the present rejection, namely, the inclusion of a method of preventing neoplastic development comprising administering phospholipase A2 alone is no longer covered by claim 5. The issues addressed in the Office Action relate to the inclusion in claim 5 of administration of a vaccine comprising phospholipase A2 alone. Accordingly, since claim 5 has been amended as set forth above to delete the subject matter

regarding which the U.S. PTO has made objections, the subject matter remaining in claim 5, against which the U.S. PTO has raised no objection for enablement, overcomes the present rejection. Accordingly, reconsideration and withdrawal of this rejection are requested.

The applicant respectfully notes that the expression "misleadingly interpretes" in the February 26, 2003 Office Action, page 6, line 13, appears to suggest that the applicant has misinterpreted the statements by the Examiner, as the Office Action does not identify any statement by the applicant that the Examiner deems to be misleading.

With respect to the comments by the Examiner that the specification does not describe how to determine whether a particular individual is at risk of tumor development, it is respectfully noted that persons of skill in the art are very familiar with techniques for assessing risk of tumor development. Similar to *any* vaccine, the skilled artisan is readily familiar with assessing whether a particular patient is at risk of developing any particular disorder, and based on such an analysis, making a decision regarding whether to administer to such patient a vaccine for such disorder. Many vaccines are recommended to be administered to *all* patients, regardless of whether the patients are deemed to be at higher relative risk of developing the disorder to which the vaccine is directed. The lack of a means for accurately predicting exactly which persons would have developed the disorder does not reduce the benefits provided to society by such treatments. The same applies to the comments by the Examiner regarding the timing of precisely when a patient might start to suffer from a disorder.

Claims 5, 43, 44, 46 and 47 were rejected under 35 U.S.C. § 112, first paragraph, "scope." The comments in the February 26, 2003 Office Action relating to this issue are directed to the inclusion of a method comprising administering a vaccine consisting of phospholipase A2 enzymes (or part thereof) alone. As discussed above, claim 5 has been amended to delete coverage of a method comprising administering a vaccine comprising phospholipase A2 (or part thereof) alone. Accordingly, as above, since the U.S. PTO has not objected to the subject matter now remaining in claim 5, the alleged basis for this rejection has been eliminated, and accordingly, reconsideration and withdrawal of this rejection are requested.

In view of the above, claims 5, 43 and 47 are in condition for allowance.



If the Examiner believes that contact with Applicant's attorney would be advantageous toward the disposition of this case, the Examiner is herein requested to call Applicant's attorney at the phone number noted below.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1446.

Respectfully submitted,

Kevin C. Brown  
Reg. No. 32,402

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Date

KCB:jms

BURR & BROWN  
P.O. Box 7068  
Syracuse, NY 13261-7068

Customer No.: 025191  
Telephone: (315) 233-8300  
Facsimile: (315) 233-8320